OCT 16 2003

K031278

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Endoscopes and Accessories
Common and Usual Name:	Endoscope, Ureteroscope
Proprietary Name:	Stryker Flexible Ureteroscope

This 510(k) summary and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker Flexible Ureteroscope is substantially equivalent in safety and efficacy to the currently marketed Karl Storz Uretero Fiberscope (KSEA11273) as cleared under 510(k) #K970427.

The Stryker Flexible Ureteroscope is a newly marketed product for Stryker Endoscopy and is based upon technology used in endoscope production and clinical applications for over 30 years. All applicable materials are tested and validated for biocompatibility according to the voluntary standard ISO 10993 "Biological Evaluation of Medical Devices". The cleaning, disinfection, and sterilization methods will be equivalent to those for which the Karl Storz Uretero-Fiberscope is currently validated. The Stryker Flexible Ureteroscope will be electrically isolated from the patient and the physician, will meet safety standards for leakage current, will not present a thermal hazard to the patient or the physician, and will meet all applicable safety standards established by EN 60601-2-18: Particular Requirements for the Safety of Endoscopic Equipment.

The Stryker Flexible Ureteroscope will conform to the following voluntary standards: EN 550 Ethylene Oxide Sterilization; ISO 10993: Biological Evaluation of Medical Devices.

There are no significant technological differences between the Stryker Flexible Ureteroscope and the predicate Karl Storz Uretero-Fiberscope. Clinical data and laboratory testing demonstrate that the differences do not raise new issues of safety and effectiveness of the proposed device. Therefore, the Stryker Flexible Ureteroscope is substantially equivalent to the currently marketed Karl Storz Uretero-Fiberscope.

Contact:

CT CK 4/17/03

Christopher L. Cook — Date
Quality Engineer
Stryker Endoscopy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Mr. Christopher L. Cook
Quality Engineer
Stryker® Endoscopy
5900 Optical Court
SAN JOSE CA 95138

Re: K031278
Trade/Device Name: Stryker Flexible Ureteroscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FGB
Dated: August 20, 2003
Received: August 21, 2003

Dear Mr. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031278

Appendix H

Indications for use statement

18 April, 2003

510(k) Number: K031278

Device Name: Stryker Flexible Ureteroscope

INDICATION FOR USE:

The Stryker Flexible Ureteroscope is indicated for use during minimally invasive urological procedures accessed through natural body orifices and is intended for, but not limited to transurethral examination of the upper urinary tract including the ureter, and kidney and, utilizing additional accessories for various diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031278